Appendix J
Quality Assurance Project Plan and
Quality Management Plan Checksheets

The following forms will be used to review all Quality Assurance Project Plans and Quality Management Plans in which environmental data collection activities are GLNPO's responsibility. These forms are very similar to review forms used in EPA Regions 10 and 3.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
GREAT LAKES NATIONAL PROGRAM OFFICE
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

TO: , PROJECT OFFICER

THRU: LOUIS BLUME, QA MANAGER

FROM:

SUBJECT: REVIEW OF “”

GRANT #:

DATE:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
GREAT LAKES NATIONAL PROGRAM OFFICE
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

QUALITY ASSURANCE PROJECT PLAN CHECKSHEET

Revision: ___ QAPP Category: ____ Project Number: _____

GRANT TITLE:

Author/P.I.: _____ Project Officer: _____

Date Review Submitted: _____ Date Review Requested: _____

Date Review Completed: _____ Reviewed by: _____

Major (X) and/or minor (O) deficiencies, defined here as the absence of relevant or incomplete information, were found in the following elements:

___ Title & Approval Sheet	___ Analytical Methods
___ Table of Contents	___ Quality Control
___ Distribution List	___ Instrument/Equipment Testing
___ Project/Task Organization	___ Instrument Calibration & Frequency
___ Problem Definition/Background	___ Inspection/Acceptance for Supplies
___ Project/Task Description	___ Data Acquisition (Non-Direct)
___ Data Quality Objectives	___ Data Management
___ Special Training/Certification	___ Assessments & Response Actions
___ Documentation & Records	___ Reports to Management
___ Sampling Process Design	___ Data Review, Validation, & Verification
___ Sampling Method	___ Validation and Verification Methods
___ Sample Handling	___ Reconciliation with User Requirements

See attached sheets for discussion comments relative to all elements.

Conclusion/Recommendation:

____ Acceptable ____ Acceptable with minor revisions ____ Unacceptable with major revisions

	IA	IU	NI	NA	COMMENTS	
A1. Title & Approval Sheet						
Title						
Organization's name						
Dated signature of project manager						
Dated signature of QA officer						
Other signatures, as needed						
A2. Table of Contents						
A3. Distribution List						
A4. Project/Task Organization						
Identifies key individuals with their responsibilities (e.g., data users, decision makers, project QA manager, Subcontractors, etc.)						
Organization chart shows lines of authority & reporting responsibilities						
A5. Problem Definition/Background						
Clearly states problem or decision to be resolved						
Historical & background information						
A6. Project/Task Description						
Lists measurements to be made						
Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives						
Notes special personnel or equipment requirements						
Provides work schedule						
Notes required project & QA records/reports						
A7. Quality Objectives & Criteria for Measurement Data						
States project objectives and limits, both qualitatively & quantitatively						
States & characterizes measurement quality objectives as to applicable action levels or criteria						
A8. Special Training Requirements/Certifications						
A9. Documentation & Records						
Lists information & records to be included in data report (e.g. raw data, field logs, results of QC checks, problems encountered)						
States requested lab turnaround time						
Gives retention time and location for records and reports						

	IA	IU	NI	NA	COMMENTS
B1. Sampling Process Design (Experimental Design)					
Types and number of samples required					
Sampling network design & rationale for design					
Sampling locations & frequency of sampling					
Sample matrices					
Classification of each measurement parameter as either critical or needed for information only					
Validation study information, for non-standard situations					
B2. Sampling Method Requirements					
Identifies sample collection procedures & methods					
Lists equipment needs					
Identifies support facilities					
Identifies individuals responsible for corrective action					
B3. Sample Handling & Custody Requirements					
Notes sample handling requirements					
Notes chain of custody procedures, if required					
B4. Analytical Methods Requirements					
Identifies analytical methods to be followed (with all options) & required equipment					
Provides validation information for non-standard methods					
Identifies individuals responsible for corrective action					
B5. Quality Control Requirements					
Identifies QC procedures & frequency for each sampling, analysis, or measurement technique, as well as associated acceptance criteria and corrective action					
References procedures used to calculate QC statistics (e.g., precision, bias, accuracy)					
B6. Instrument/Equipment Testing, Inspection, and Maintenance Requirements					
Identifies acceptance testing of sampling and measurement systems					
Describes equipment needing calibration and frequency for such calibration					
Notes availability & location of spare parts					

	IA	IU	NI	NA	COMMENTS	
B7. Instrument Calibration & Frequency						
Identifies equipment needing calibration and frequency for such calibration						
Notes required calibration standards and/or equipment						
Cites calibration records & manner traceable to equipment						
B8. Inspection/Acceptance Requirements for Supplies & Consumables						
States acceptance criteria for supplies & consumables						
Notes responsible individuals						
B9. Data Acquisition Requirements for Non-Direct Measurements						
Identifies type of data needed from non-measurement sources (e.g., computer data bases and literature files), along with acceptance criteria for their use						
Describes any limitations of such data						
B10. Data Management						
Describes standard record keeping & data storage and retrieval requirements						
Checklist or standard forms attached to QAPP						
Describes data handling equipment & procedures used to process, compile and analyze data (e.g., required computer hardware & software)						

C1. Assessments & Response Actions					
Lists required number, frequency, & type of assessments, with approximate date & names of responsible personnel					
Identifies individuals responsible for corrective actions					
C2. Reports to Management					
Identifies the preparer and recipients of reports					
Identifies frequency and distribution of reports for:					
Project status					
Results of performance evaluations & audits					
Results of periodic data quality assessments					
Any significant QA problems					

IA = Included & Acceptable NI = Not Included IU = Included & Unacceptable NA = Not Applicable	IA	IU	NI	NA	COMMENTS	PAGE 5 OF 5
D1. Data Review, Validation, & Verification						
States criteria for accepting, rejecting, or qualifying data						
Includes project-specific calculations or algorithms						
D2. Validation and Verification Methods						
Describes process for data validation and verification						
Identifies issue resolution procedure and responsible individuals						
Identifies method for conveying these results to data users						
D3. Reconciliation with User Requirements						
Describes process for reconciling with DQOs and reporting limitations on use of data						

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
GREAT LAKES NATIONAL PROGRAM OFFICE
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

QUALITY MANAGEMENT PLAN CHECKSHEET

Revision: ____ __ Project Number: _____

TITLE:

Author/P.I.: _____ Project Officer: _____

Date Review Submitted: _____ Date Review Requested: _____

Date Review Completed: _____ Reviewed by: _____

Major (X) and/or minor (O) deficiencies, defined here as the absence of relevant or incomplete information, were found in the following elements:

___	Management & Organization	___	Procurement of Items and Services
___	Organization's QA Policy Statement	___	Procurement Document Approval
___	Distribution List	___	Solicitation Response Approval
___	QA Manager/Staff Authorities	___	Documents & Records
___	Technical Activities/Programs	___	Computer Hardware & Software
___	Quality System Components	___	Planning
___	Principle Components	___	Implementation of Work Processes
___	Tools for Implementing Components	___	Assessment & Response
___	Personnel Qualification and Training	___	Quality Improvement

See attached sheets for discussion comments relative to all elements.

Conclusion/Recommendation:

___ Acceptable ___ Acceptable with minor revisions ___ Unacceptable with major revisions

IA = Included & Acceptable NI = Not included IU = Included & Unacceptable NA = Not Applicable	IA	IU	NI	NA	COMMENTS
A1. Management & Organization					
Title Page					
Organization's name					
Dated signature of project manager					
Dated signature of QA officer					
Other signatures, as needed					
A2. Organization's QA Policy Statement					
Importance of QA and QC					
General objectives and goals of a quality system					
Policy for resource allocation for the quality system					
A3. Distribution List					
Identifies key individuals with their responsibilities (e.g., data users, decision makers, project QA manager, Subcontractors, etc.)					
Organization chart shows lines of authority & reporting responsibilities					
A4. QA Manager/Staff Authorities					
Documents the organizational independence of the QA Manager from groups generating, compiling, and evaluating environmental data					
Indicates how the organization will ensure that QA personnel will have access to the appropriate levels of management in order to plan, assess, and improve the organization's quality system					
A5. Technical Activities/Programs					
States the specific programs that require quality management controls					
States where oversight of delegated, contracted, or other extra mural programs are needed to assure data quality					
States where and how internal coordination of QA and QC activities among the group's organizational units needs to occur					

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B1. Quality System Components					
Description of the organization's quality system					
B2. Principle Components					
A description of the principle components of the organization's quality system in terms including the roles and responsibilities of management and staff:					
Quality system documentation					
Annual systems review					
Management assessments					
Training					
Systematic planning of projects					
Project-specific quality documentation					
Project and data assessments					
B3. Tools for Implementing Components					
QMP's					
Quality system audits					
Training plans					
QAPP					
Data verification and validation					
A list of components of the organization that develop QAPP's in support of the organization's quality system and the review and approval procedures for such documentation					
A discussion of how roles and responsibilities for the principal components of the quality system are incorporated into performance standards					
C1. Personnel Qualification & Training					
A statement of the policy regarding training for management and staff					
A description of the process(es), including the roles, responsibilities, and authorities of management and staff for:					
Identifying, ensuring, and documenting that personnel have maintained the appropriate knowledge, skill, and statutory, regulatory, professional or other certifications, accreditation, licenses, or other formal qualification necessary					
Identifying the need for retraining based on changing requirements					

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D1. Procurement of Items & Services					
Describes or references the process(es), including the roles, responsibilities, and authorities of management and staff, pertaining to all appropriate procurement documents or extra mural agreements, including grants, cooperative agreements, and contracted and subcontracted activities, involving or affecting environmental programs					
D2. Procurement Document Approval					
Reviewing and approving procurement documents to ensure that procurement documents are accurate, complete, and clearly describe:					
The item or service needed					
The associated technical and quality requirements					
The quality system elements for which the supplier is responsible					
How the supplier's conformance to the customer's requirements will be verified					
D3. Solicitation Response Approval					
Review and approval of all applicable responses to solicitations to ensure that these documents:					
Satisfy all technical and quality requirements					
Provide evidence of the supplier's capability to satisfy EPA quality system requirements as defined in the extra mural agreement or applicable Federal Regulation					
Ensuring that procurement items and services are of acceptable quality, including the review of objective evidence of quality for applicable items and services furnished by suppliers and subcontractors, source selection, source inspections, supplier audits, and examination of deliverables					
Review and approval procedures for mandatory quality-related documentation (e.g., QMP's or QAPP's) from suppliers					
Policies and criteria for delegations of EPA authority to review and approve mandatory quality-related documentation (e.g., QMP's or QAPP's) from suppliers consistent with Chapter 2.2 of EPA Order 5360					

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Ensure that EPA quality-related contracting policies, as defined by the Federal Acquisition Regulations Office of Federal Procurement Policy, and the EPA Contracts Management Manual [EPA Order 1900(EPA 1998)]					
E1. Documents and Records					
Describes or references the process(es) including roles, responsibilities, and authorities of management and staff for:					
Quality-related documents and records requiring control					
Records and documents accurately reflect completed work					
Established chain of custody					
Ensure compliance with all applicable statutory, regulatory, and EPA requirements for documents and records					
Establish and implement confidentiality procedures for evidentiary records					
F1. Computer Hardware and Software					
Describes or references the process(es) including roles, responsibilities, and authorities of management and staff for:					
Assessed and documented the impact of change to user requirements and/or the hardware and software					
Evaluated purchased hardware and software to ensure it met user requirements and complied with applicable and contractual requirements and standards					
Ensured that data and information produced from, or collected by, computers met applicable information resource management requirements and standards					
Developed, installed, and tested documenting hardware and software used in environmental programs to ensure it met technical and quality requirements and directives from management					
Ensured that applicable EPA requirements for information resources management were addressed					

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G1. Planning					
Describes or references the process(es) including roles, responsibilities, and authorities of management and staff for planning environmental data operations using a systematic planning process which includes:					
Identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, and scientific experts					
Description of the project goal, objectives, and questions and issues to be addressed					
Identification of project schedule, resources, milestones, and any applicable requirements					
Identification of the type and quality of data needed and how the data will be used to support the project's objective					
Specifications of performance criteria for measuring quality					
H1. Implementation of Work Processes					
Describes or references the process(es), including roles, responsibilities, and authorities of management and staff for:					
Ensuring that work is performed according to approved planning and technical documents					
Identification of operations needing procedures, preparation, review, approval, revision, and withdrawl of these procedures; and policy for use					
Controlling and documenting release, change, and use of planned procedures, including any necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed					
I1. Assessment and Response					
Describes or references the process(es) including roles, responsibilities, and authorities of management and staff for:					
Assesses the adequacy of the quality system at least annually					
Plans, implements, and documents assessments and reporting assessment results to management including how to select an assessment tool, the expected frequency of their application to environmental programs, and the roles and responsibilities of the assessors					

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Determines the level of competence, experience, and training necessary to ensure that personnel conducting assessments are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed					
Ensures that personnel conducting assessments have sufficient access to programs, manager, documents, and records					
Management's review and response to assessment					
Identifies how and when corrective actions are to be taken in response to the findings of the assessment, ensuring corrective actions are made promptly, confirming the implementation and effectiveness of any corrective action, and documenting such actions					
Addresses any disputes encountered as a result of assessments					
J1. Quality Improvement					
Identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities and describes the process to ensure continuous quality improvement, including the roles and responsibilities of management and staff					
Ensures that conditions adverse to quality are:					
Prevented					
Identified promptly including a determination of the nature and extent of the problem					
Corrected as soon as practical, including implementing appropriate corrective actions and actions to prevent reoccurrence					
Documenting all corrective actions					
Tracking such actions to closure					
Encourages staff at all levels to establish communications between customers and suppliers, identify process improvement opportunities, and identify and offer solutions to problems					